REMARKS

The above amendments have been provided based on the format described at 1265 Off. Gaz. Pat. Office 87 (December 17, 2002) and as authorized by Deputy Commissioner for Patents, Stephen Kunin on January 31, 2003.

Claims 2-5 and 15-27 were rejected. Claims 2, 3, 5, 15, 19, 25, and 27 have been amended herein in light of business-related reasons and not in acquiescence to any rejection made by the Office. Support for the amendments can be found at page 12, lines 12-19 (suppression of T cell activation); and page 19, page 3, line 42 - page 4, line 2 (reduced T cell stimulatory capacity of antigen presenting cells). Therefore, the current amendments are not believed to present any new matter. Claims 2-5 and 15-27 are presently pending. No claim has been allowed.

Applicants gratefully acknowledge the withdrawal of the objections and the rejection under 35 U.S.C. § 102(b). Applicants also gratefully acknowledge that claims 20-22 are properly viewed as in compliance with 35 U.S.C. § 112, first paragraph and that claims 3, 4, 19 and 20 are properly viewed as in compliance with 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Although the Action states that claim 23 is rejected under 35 U.S.C. § 112, second paragraph, the language of the rejection indicates that the rejection is an enablement rejection under 35 U.S.C. § 112, first paragraph. Therefore, the rejection is addressed herein as an enablement rejection under the first paragraph of 35 U.S.C. § 112. If Applicants have misunderstood the Examiner's rejection, Applicants respectfully request clarification.

According to the Action, the instant specification does not provide enablement for introducing T cells to the recipient or administering IL-10 to the tissue to be transplanted before transplantation as claimed in claim 23. The Action asserts that the specification does not show a safe or effective way of suppressing the immune response. Applicants respectfully traverse this rejection.

The specification fully enables claim 23. First, the specification discloses the introduction of T cells to a recipient as well as administering IL-10 to a tissue to be transplanted. As one example, the Examiner's attention is directed to the specification at page 5, lines 4-9, which reads in part:

> ... when the immune response accompanies tissue transplantation, the administering is prior to the tissue transplantation; the ***T cell is introduced into the recipient***; or ***IL-10 is administered to the tissue to be transplanted before the transplantation*** ...

Second, Applicants are not required to provide evidence of safety to satisfy the enablement requirement. "[C]onsiderations made by the FDA for approving clinical trials are different from those made by the PTO in determining whether a claim is enabled." MPEP § 2164.05. Therefore, the standard cited by the Office is not appropriate for the enablement analysis. Applicants respectfully submit that the disclosure provided in the specification provides sufficient guidance to a skilled artisan.

Claims 2-5 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to reasonably provide enablement for a method of inhibiting all possible antigen-specific responses of an immune response by administering IL-10 and an antigen. The Action asserts that the claim does not differentiate between a cellular and humoral immune response, and therefore that this lack of differentiation may result in severe consequences if an incorrect immune response is induced or suppressed. Therefore, the Action concludes one of skill in the art would not be able to predict whether the administration of IL-10 with an antigen would inhibit an immune response that is not mediated by a T cell. Applicants respectfully traverse these rejections.

Applicants submit that a distinction between the humoral and cellular response as the target of the claimed methods is not required because inhibition of a T cell response can inhibit both a humoral immune response as well as a cellular immune response. First, the claimed methods are exemplified using assays analyzing T cell activation (*e.g.*, MLR) and using claimed agents that exclusively activate T cells (*i.e.*, anti-CD3). Second, highly purified human T cells are used *ex vivo* in many of the assays exemplifying the claimed methods. (*See, e.g.*, Example

4). Therefore, skilled artisans would recognize the cell inhibited by the claimed methods as a T cell. As T cells play a critical role in both the humoral (*e.g.*, CD4+ helper cell) and cellular (*e.g.*, CD4+ helper and CD8+ cytotoxic cells) immune responses, both responses can be modulated using the cells of the claimed methods. Nonetheless, Applicants have amended claims to further clarify the T cell as the cell suppressed by IL-10 in the presence of antigen and/or anti-CD3.

In light of the above remarks, Applicant respectfully submits that the rejections under 35 U.S.C. § 112, first paragraph, are overcome. Therefore, Applicants request the withdrawal of the rejection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 2, 5, and 15 are rejected under 35 U.S.C. § 112, second paragraph for reasons of record. Applicants respectfully traverse this rejection for reasons discussed below.

According to the Action, it is unclear who or what the IL-10 is being administered to in claim 2. Claim 2 is amended herein to clarify that IL-10 is being administered to a T cell.

The Action also asserts that it is unclear what stimulatory capacity of the cells in claim 5 is reduced. Claim 5 is amended herein to clarify that the stimulatory capacity reduced by IL-10 is the capacity to stimulate T cells.

The Action further asserts that it is unclear how the combination of IL-10 and either the antigen or anti-CD3 are administered into a cell with respect to claim 15. Claim 15 is amended herein to clarify that the combination of IL-10 and either antigen or anti-CD3 is administered to a T cell.

Claims 25-27 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. According to the Action, it is unclear how the combination of IL-10 and either the antigen or anti-CD3 is administered into an immune system. The Action asserts that it is the meaning of "precursor to said T cell" in claim 27 is unclear. Claim 25 is amended herein to clarify the administration of IL-10 and either antigen and anti-CD3 is to precursor T cells. Claim 27 is amended herein to clarify the language identifying the T cell precursor.

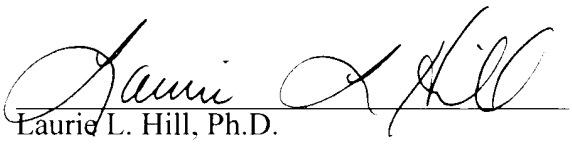
In light of the above remarks, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, second paragraph is overcome. Therefore, Applicants request the withdrawal of these rejections.

CONCLUSION

Applicants respectfully submit that the rejections under 35 U.S.C. § 112 have been overcome by the above remarks. Early allowance of pending claims 2-5 and 15-27 is respectfully requested. In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942000101.

Respectfully submitted,

Dated: April 2, 2003

By: 

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